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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-UW2220
P O BOX 1539
KING OF PRUSSIA PA 19406-0939

EXAMINER

BERCH, M

ART UNIT	PAPER NUMBER
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1611

DATE MAILED:

01/28/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/265,926

Applicant(s)

Dates

Examiner

Mark L. Berch

Group Art Unit
1611



☒ Responsive to communication(s) filed on Dec 20, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 5-7 and 10-20 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 5-7 and 10-20 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Applicants are reminded that this case is SN 09/265,926.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7 and 10-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The reasons were given previously; the traverse on this point is unpersuasive. The fact that claim 10 is narrower than original claim 1 does not mean that there cannot be a description issue. If applicants had originally said, "I claim organic compounds" applicants could not then add later whatever species they like in new claims on the theory that they fall within the ambit of "organic compounds".

In this case, the concept of doing the synthesis with the final step as an hydrolysis did not exist in this specification. Claim 8 as stated previously provides descriptive support of doing the final step as a hydrogenolysis. Applicants point to EP 141927, paragraph bridging pages 6-7, saying, "The specification provides details to be found in EP 141927 and EP 141644." Such a statement is simply not accurate

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insofar as it refers to EP 141927. The only mention of EP 141927 is on page 1 of the specification, where it states that ACP (the starting material for the current claims) is disclosed in EP 141927. A mention of a starting material source is not the same thing as a mention of a procedure to be done in the last step of a reaction. Thus, this application has no statement that a step in EP 141927 is to be used in the current process. Applicants state, "The dechlorination via hydrolysis is not a new process step." That is irrelevant. What matters is whether this specification teaches that the overall process, which has 4 or 5 steps, can be done with an hydrolysis in the final step.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5 and 15-19 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 302,644.

The reasons were given previously; the traverse on this point is unpersuasive. It is clear that an impasse has been reached on this issue. Applicants continue to view the reference solely in terms of a working example, as if nothing else exists in the document. The position has no basis in patent law. A reference is available for all that it teaches, not just the best or even the preferred embodiments. In this regard, see *In*

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re Lamberti, 192 USPQ 278, 280; *In re Boe*, 148 USPQ 507, 510; *In re Fracalossi*, 215 USPQ 569, 570. The process as described does not require that the Cl be removed prior to decarboxylation, despite what applicants list as the steps of the reference in the middle of page 3 of the remarks. The initial coupling in the first step gives VI. Then there is a decarboxylation, given at page 6, line 49, first word. The scheme does not require, indeed, does not even mention, removing the 6-Cl prior to decarboxylation. The failure to mention removal of Cl between the two steps would indeed qualify as “clearly and unequivocally” (remarks, page 4) teaching one of ordinary skill in the art that the process can be done in exactly that way, can be done without an intervening step. Thus, applicants description of the reference solely in terms of coupling then dechlorination then decarboxylation simply ignores what is on page 6. Indeed, it is only later in the line that the option of changing other variables is mentioned. One who follows this scheme (that is, does the coupling, then the decarboxylation) then moves on to step (ii) which involves reducing the ester to the CH₂OH group (page 6, line 52) and the final step of acylating (line 53). Nowhere does the scheme require removal of the 6-substituent.

The remarks state, “The process steps on pages 5 and 6 of the ‘644 reference do not teach when the starting material ... is to be dechlorinated.” If that is so, why do applicants insist that the reference requires that the 6-Cl be removed as the second step? The examiner again points out that the anticipated claims do not have the step of removing the Cl. Thus, by pointing to the scheme which does not require the 6-Cl to

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be removed, claims which do not remove the 6-Cl are anticipated. To put it differently, insofar as the anticipation is concerned, step (e) does not belong in the discussion because that step (e) is not present in the anticipated claims.

In summary, the correct view of the prior art is that steps a), c), d) and e) describe the prior art process as set forth on pages 5-6, and that the anticipated claims have steps a), b), c) and d). These two sets are the same. The first sentence on page 4 of the remarks is thus not correct for the anticipated claims, because the final step for these claims is step d), not the removal of the 6-Cl. Claim 15 starts with a 6-Cl and ends with it as well.

Discussion of isolation steps is irrelevant. The claims are silent on the subject of isolation steps or their lack, and lack of anticipation cannot be based on limitations not present in the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5 -7 and 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 302,644.

The reasons were given previously; the traverse on this point is unpersuasive.

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Applicants will be presenting a declaration, but this has not yet been received. The annex is noted but is far too fragmentary to evaluate. For example, the examiner previously noted in point B that different reduction procedures were done in the prior art vs the claimed process, but one cannot tell from this annex whether this is still so.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mark L. Berch whose telephone number is 703-308-4718.

Mark L. Berch



Primary Examiner

Group 1610 - Art Unit 1611

January 21, 2000